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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,944	08/28/2003	Itzhak Bentwich	050992.0300.CPUS08	1943
37808	7590	11/06/2006	EXAMINER	
ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			DEJONG, ERIC S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/604,944	Applicant(s) BENTWICH, ITZHAK	
	Examiner Eric S. DeJong	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006 and 16 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,11,12,14,23 and 26 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,11,14,23 and 26 is/are rejected.
- 7) ☒ Claim(s) 12 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/31/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicants submission of a declaration of Dr. Eti Meirie under 37 C.F.R. § 1.132 on 8/16/2006 is acknowledged.

Claim Objections

Claims 12 and 14 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1 and 26. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 12 is drawn to a probe consisting of the nucleic acid of claim 1 or claim 26, which is identical in scope to the nucleic acids claimed in either of claims 1 and 26. Further, the "gene expression detector" as recited in line 2 of claim 14 has been treated as the probe of claim 12. Therefore, the composition set forth in claim 14 is identical in scope to the nucleic acids as claimed in either of claims 1 and 26.

Claim Rejections - 35 USC § 112

The previous rejection of claims 1, 8, 11, 12, 14, 23, and 26 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of amendments made to the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "(a) gene expression inhibition system" in line 1 of said claim. Claim 14 recites the limitation "(a) gene expression detection system" in line 1 of said claim. However, it is unclear what statutory category the instant claims are directed towards as the recitation of the term "system" encompasses both a composition and a process. MPEP 2173.05(p) states:

"A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551."

For the purpose of continuing examination, claims 11 and 14 have been construed to be drawn to only a composition.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. § 101.

Double Patenting

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention

claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

Claims 1, 8, 11, 12, 14, 23, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, and 14 of copending Application No. 10/536,560; claims 1-8, 12, and 14 of copending Application No. 10/605,838; claims 1-8, 12, and 15 of copending Application No. 10/605,840; claims 1-8, 12, and 14 of copending Application No. 10/707,003; claims 1, 2, and 4 of copending Application No. 10/708,952; and claims 1, 2, and 5 of copending Application No. 10/709,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identified claims in the above copending applications are generically drawn to a plurality sequences that are provided for in their respective disclosure. Since the above identified copending applications are related as child applications of the instant application (parent), the nucleotide sequences disclosed therein encompass SEQ ID No. 14 as claimed in the instant application. Therefore the instant claims, which are specific to SEQ ID No. 14,

are encompassed by the claimed compositions of the above identified copending applications that are drawn to a generic nucleic acid sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 12, and 14 under 35 U.S.C. 102(b) as being anticipated by Brander et al. is withdrawn in view of amendments made to the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Brander et al.

The claims are drawn to a vector comprising SEQ ID No. 14, a gene expression inhibition systems comprising said vector and a means for inserting said vector into a cell, and an isolated nucleic acid complementary to the nucleic acid consisting of 77 to 120 nucleic acids wherein said nucleic acid further comprises SEQ ID No. 14.

[Claims 8 and 11]: Brander et al. discloses the isolation of HIV-1 viral sequences from the Gag p17 region (gag) gene. The submission to Genbank under accession number AF017925 contains the sense and antisense sequences of the Gag p17 region

that comprises a 77 contiguous nucleotide region with 100% identity to that of the elected sequence, SEQ ID No. 14 (see Brander et al., page 2560, col. 2., lines 38-46). Brander et al. further discloses that identified gag genes were isolated using routine molecular cloning techniques relying on PCR and cell transformations involving vector constructs containing the disclosed sequences (see Brander et al. pg 2560, col. 1, line 5 through col. 2, line 37), which reads on the instantly claimed means for inserting said vector into a cell. The instantly claimed "vector comprising an HIV nucleic acid, wherein the HIV nucleic acid consists of the nucleic acid of claim 1 or 26" remains open to embodiments wherein the vector comprises recited HIV nucleic acid as well as additional nucleic acid sequences. Therefore, the disclosed vector of Brander et al. comprising a HIV nucleic acid comprising a region with 100% sequence identity to that of SEQ ID No. 14 reads on the instantly claimed limitations drawn to a vector comprising an HIV nucleic acid consisting of SEQ ID No. 14.

[Claim 23]: The scope of instantly claimed isolated nucleic acid complementary to the nucleic acids of instant claims 1 and 26 is not expressly limited to embodiments wherein the complementary nucleic acid is the complement to the nucleic acids set forth in instant claims 1 and claim 26. For example, paragraph 0020 of the instant specification sets forth a preferred embodiment comprises: "synthesizing a complementary nucleic acid molecule, a nucleic sequence of which complementary nucleic acid molecule is a partial inversed-reversed sequence of said RNA, and transfecting host cells with the complementary nucleic acid molecule, thereby complementarily binding said RNA." Therefore, the scope of the complementary nucleic

acid sequence recited in instant claim 23 is taught as encompassing larger polynucleotides that contain sequence domains that are either fully or partially complementary to the nucleic acid sequences as set forth in instant claims 1 and 26. The disclosed antisense sequence of the Gag p17 region further comprises a 77 contiguous nucleotide region that is a perfect complement to that of SEQ ID No. 14 and, therefore, reads on the instantly claimed isolated nucleic acid complementary to SEQ ID No. 14.

Response to Arguments

Applicant's arguments filed 07/31/2006 and 08/16/2006 have been fully considered but they are not persuasive.

In regards to the provisional rejection of claims 1, 8, 11, 12, 14, 23, and 26 on the ground of nonstatutory obviousness-type double patenting, applicants argue that the only outstanding rejection is the obviousness-type double patenting rejection.

In response, it is noted that claims 12 and 14 are objected to and 8, 11, 14, and 23 are rejected on grounds other than nonstatutory obviousness-type double patenting. Therefore the provisional rejection of claims 1, 8, 11, 12, 14, 23, and 26 has been maintained.

In regards to the rejection of claims 8, 11, and 23 under 35 U.S.C. 102(b) as being anticipated by Brander et al., applicants argue that the 451 nucleotide sequence set forth under accession number AF017925 is distinct from the SEQ ID 14 in that the

451 nucleotide sequence is not limited to a nucleic acid sequence consisting of 77 to 120 nucleotides as instantly claimed.

In response it is noted that nucleic acid constructs recited in claims 8, 11, and 23 are not limited a nucleic acid sequence consisting of 77 to 120 nucleotides, but rather are open to embodiments wherein the claimed compositions comprise the nucleic acid sequence of instant claims 1 and 23 and, therefore, are not limited to a nucleic acid sequence consisting of 77 to 120 nucleotides. For the benefit of applicant, it is noted that amending claim 8 to recite -- an HIV nucleic acid insert, wherein the HIV nucleic acid insert -- in lines 1 and 2 of said claim would be sufficient to overcome the instant rejection of claims 8 and 11. For the benefit of applicant, it is further noted that amending claim 23 to recite --An isolated nucleic acid complement of the nucleic acid of claim 1 or 26, wherein said isolated nucleic acid complement is identical in length to the nucleic acid of claim 1 or 26-- would be sufficient to overcome the instant rejection of claim 23.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ

John S. Brusca 27 October 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER